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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/227,854	01/11/1999	JIAN NI	PF210D1	7606

22195 7590 07/30/2002

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EXAMINER	
PRASAD, SARADA C	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 07/30/2002 18

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Acti n	Applicati n N .	Applicant(s)	
	09/227,854	NI ET AL.	
	Examiner	Art Unit	
	Sarada C Prasad	1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 July 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *03 July 2002*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☒ Applicant's reply has overcome the following rejection(s): *see attached*.

4.☒ Newly proposed or amended claim(s) *35-54, 60-70* would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☐ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *35-54 and 60-70*.

Claim(s) withdrawn from consideration: _____.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

Advisory Action

1. Receipt of Applicant's arguments and amendments filed in Paper No. 17 (7/3/02) is acknowledged. As per applicants' request, amendments to claims .... And amendments to specification have been entered. Currently claims 35-54, and 60-70 are pending and are under consideration for examination. Declaration under 37 CFR 1.131, submitted in Paper No. 9 (4/2/01) by Ni et al. has been entered and acknowledged.

2. Applicant's arguments filed in Paper No. 17 (7/3/02), have been fully considered but were deemed persuasive in part.

Based on the applicants' response the following rejection/objections are withdrawn.

(i) objection to specification based on incorrect brief description to figure 3;

(ii) rejection of claims 35-54, and 60-70 under 35 USC 112-first paragraph based on lack of adequate written description;

(iii) rejection of claims 35-59 under 35 USC 102 (e) as being anticipated by Hitomi et al.

3. The issues remaining issues, are stated below. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112-First Paragraph

4. Claims 35-54, and 60-70 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record set forth in the office action of 1/29/02, Paper No. 15 and reiterated as follows.

The rejection is based on the grounds that the applicants have not taught how to use the instant portions and variants of polypeptide of SEQ ID No. 2 that might not retain chemotactic activity in ways such as .....and that it would be undue experimentation. Applicants assert that 'there is no limitation in the instant claims requiring that the claimed polypeptides be functionally equivalent to the full-length CCI polypeptide (3rd para of page 7 of paper NO. 17). .....It is improper to read a limitation into a claim from the specification'. At the same time applicants also emphasize that' the specification enables the use of the claimed polypeptides that retain the biological activity of the full length CCI polypeptide, and teaches the use of the claimed polypeptides that do not require such activity, for example as immunogens for antibody preparation' (page 8, entire 2nd para of paper No. 17).

These two arguments have not been found to be persuasive and the Examiner's response is as follows: While the specification discloses chemotactic activities of the full length CCI - polypeptide and is enabled for that embodiment alone, the specification is not enabled for the embodiment that comprises portions of the polypeptide that need not necessarily be active. Applicants assert that such portions of amino acid sequences comprising contiguous stretches of SEQ ID NO. 2 with no activity may be used to make antibodies. This argument is not persuasive because it is not predictable that such antibodies directed to 'portions of even a well known/established protein' would necessarily identify the full length, native protein, because the epitopes to which the antibodies are directed to could reside in other unrelated proteins comprising similar streches of epitopes. Thus the enablement of a functional full length polypeptide can not be extrapolated to parts of the polypeptide that have no identity other than homology to stretches of the same SEQ ID No.2. It is true that with the state of the art

knowledge one of skill could make variant CCI-polypeptides, and could test for their activities. However, use of such portions of polypeptides that might not have any measurable activities is not enabled, even though the speciation teaches how to measure activities when the claimed portions exhibit such activities. The question here is one of how to use. One of skill would not know how to use the portions CCI polypeptides that do not have chemotactic activity, that do not necessarily have antigenic regions unique to CCI, because the specification fails to teach how to relate such peptides to the claimed invention. In this context, the standard of scope of enablement may be noted as follows: "the scope of protection sought in a claim bear a reasonable correlation to the scope of enablement provided by the specification, and the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation". (Vaeck, 947 F.2d at 495, 20 USPQ2d at 1444; Wands, 858 F2.d at 736-37, 8 USPQ2d at 1404; In re Fisher, 427 F2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)). Additionally, "whether making and using the invention would have required undue experimentation and thus whether the disclosure is enabling, is a legal conclusion based upon several underlying factual inquiries". See in re Wands, 858 F. 2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (fed. Cir. 1988). [emphasis added].

Based on the above discussion, one of skill would conclude that the instant specification enabled for full length polypeptide of SEQ ID No. 2 and its use for chemotatic functions, it is not enabled for use of parts of SEQ ID No. 2 that do not possess activity, nor have been recited to be bound by any functional limitations. Therefore, instant 35 USC 112 first paragraph rejection of lack of enablement is maintained.

Conclusion

7a. No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday – Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D.
Examiner
Art Unit 1646
July, 18th , 2002.

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600